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No. 06-1498

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

WARNER-LAMBERT COMPANY LLC and PFIZER INC.,

Petitioners,

v.

KIMBERLY KENT, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

HUGH F. YOUNG, JR.
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, VA 20191
(703) 264-5300

ROBERT N. WEINER
Counsel of Record
ELIZABETH J. BETTA
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, DC 20004
(202) 942-5000

Attorneys for Amicus Curiae

209878

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTIONS PRESENTED

1. Whether, under the principles articulated in *Buckman Co. v. Plaintiffs' Legal Commission*, 531 U.S. 341 (2001), federal law preempts state law where it requires, as a precondition to the imposition of liability, that the fact-finder determine whether the defendant committed fraud against a federal agency—such that it affected the agency's product approval—although the agency has not found any fraud, and the state requirement would interfere with the agency's responsibilities.

2. Whether, under *Buckman*, federal law preempts the provision in a Michigan statute that requires the fact-finder, as a prerequisite to the imposition of liability, to determine whether a manufacturer of an FDA-approved drug committed fraud against the FDA—and, "but for" the fraud, the FDA would not have approved the drug—where the FDA, itself, has not found fraud on the Agency.

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INTEREST OF *AMICUS CURIAE*[1]

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with more than 120 corporate members representing a broad cross-section of American and international manufacturers. These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective reflects the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed over 725 briefs as amicus curiae in both state and federal courts, including 66 in this Court, presenting the viewpoint of product manufacturers seeking fairness and balance in the application and development of the law.

PLAC has a significant interest in this case as the issue before the Court affects manufacturers in regulated industries, particularly pharmaceutical and medical device companies. Those effects, moreover, extend far beyond Michigan, for the question presented here regarding federal preemption may also be critical in tens of thousands of cases before state and federal courts. PLAC is well situated to address this question. The organization has filed *amicus* briefs in significant preemption cases, including *Wyeth v. Levine*, No. 2004-384, 2006 WL

1. The parties' letters consenting to the filing of this brief have been filed with the Clerk's office pursuant to this Court's Rule 37.3(a). Also, pursuant to Rule 37.6, *amicus* affirms that this brief was not authored in whole or in part by any party's counsel, nor did any person or entity other than PLAC or its counsel make a monetary contribution to the preparation or submission of this brief. A list of Corporate Members of PLAC is set forth in the Appendix.

3041078 (Vt. Oct. 27, 2006), *petition for cert. filed*, (U.S. Mar. 12, 2007) (No. 06-1249), *Buckman Co. v. Plaintiffs' Legal Commission*, 531 U.S. 341 (2001), *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Furthermore, the members of PLAC engage in commerce in all 50 states and the District of Columbia. They have faced the cross-pressures generated by divergent federal and state regulatory standards and common law rules. They have endured crushing burdens of litigation and borne liability merely for following the instructions of federal regulators. They understand—indeed, they have experienced—the practical consequences of state efforts to regulate the relationship of industries with their federal regulators. PLAC therefore can provide valuable insights on the issue before the Court.

STATEMENT

Respondents are citizens of Michigan. They sued Petitioners Warner-Lambert and Pfizer (collectively "Warner-Lambert") for injuries allegedly caused by Rezulin, a drug manufactured by Warner-Lambert and approved by the FDA for treatment of diabetes. Michigan law imposes liability on a manufacturer for injuries allegedly caused by an FDA-approved drug only if the manufacturer

> [i]ntentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the federal, food, drug, and cosmetic act . . . and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted.

Mich. Comp. Laws § 600.2946 (5)(a) (2007) (citations omitted). Thus, in order to recover damages, respondents

needed to demonstrate that Warner-Lambert knowingly concealed material facts about the safety and efficacy of Rezulin from the FDA, which would have prevented its approval or resulted in its removal from the market.

Warner-Lambert sought judgment on the pleadings because the inquiry into fraud on the FDA mandated by Michigan law invades the Agency's exclusive authority to police its relationship with regulated companies. In support of this position, Warner-Lambert relied on the Sixth Circuit's conclusion that, under *Buckman*, federal law preempts this inquiry except where the FDA itself has previously found fraud. *See Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961, 965-966 (6th Cir. 2004). The district court agreed. It found that litigation regarding fraud on the FDA would interfere with the Agency's enforcement efforts. Petition for Writ of Certiorari app. at 35a-36a, *Warner-Lambert Co. LLC v. Kent*, No. 06-1498 (U.S. May 10, 2007). The Second Circuit reversed. *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2007). Rejecting *Garcia*, the court held that *Buckman* would apply—and the predicted burdens on the FDA would occur—*only* where plaintiffs advanced a stand-alone cause of action for fraud on the Agency, not where the claim was "merely" an indispensable prerequisite to liability on another ground. *Id.* at 93-95.

SUMMARY OF THE ARGUMENT

The petition for certiorari frames a conflict between the Courts of Appeals for the Second and Sixth Circuits regarding the scope of preemption under *Buckman*. Specifically, the courts have disagreed on whether the FDA's regulation of drugs and medical devices preempts state tort claims predicated upon fraud on the FDA, or whether it preempts only stand-alone claims for such fraud. The Sixth Circuit in *Garcia* followed *Buckman* in ruling that the Michigan statute, which makes fraud against the FDA a prerequisite to liability for injuries caused by an FDA-approved product, would "inevitably conflict with the FDA's responsibility to police fraud." *Buckman*, 531 U.S. at 350; *see Garcia*, 385 F.3d at 966. The court therefore held that the statute is preempted except where the FDA itself has previously found a violation of its disclosure requirements, thereby obviating any inquiry on the subject in a tort case. *Garcia*, 385 F.3d at 966. The Second Circuit, addressing the same Michigan statute, came to the opposite conclusion. Misconstruing *Buckman*, the court rejected preemption because plaintiffs' claims were not *solely* for fraud on the FDA. *Desiano*, 467 F.3d at 93-95.

The impact of this conflict extends far beyond Michigan, and far beyond even the other seven states that similarly specify fraud on the FDA as a precondition of liability or punitive damages. Indeed, resolution of the issue before the Court will affect tens of thousands of cases seeking damages against drug and medical device manufacturers based on their dealings with the FDA. Ultimately, the proliferation of cases linking liability to the adequacy of companies' disclosures to the FDA could well upset the "somewhat delicate balance of statutory objectives" the FDA has struck in deterring and punishing fraud against the Agency. *Buckman*, 531 U.S. at 348. This Court should resolve the conflict now to avoid serious disruption and confusion.

ARGUMENT

I. The Court of Appeals' Formalistic Approach Nullifies the Key Inquiry as to Whether Claims for Fraud on the FDA Interfere with FDA Regulation

A. *Buckman* Focused on the Impact of Fraud on the FDA Claims

In *Buckman*, this Court addressed charges that a defendant had "made fraudulent representations to [the FDA] in the course of obtaining approval" to market a medical device and that "such representations were at least a 'but for' cause" of the plaintiffs' injuries. 531 U.S. at 343. At the outset of the opinion, the Court determined that no presumption against preemption applied. The Court reasoned that "policing fraud" against federal agencies was not traditionally the role of the states. *Id.* at 347. To the contrary, the Court found that "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347. Thus, the plaintiffs could not claim the benefit of the presumption.

Having decided this procedural issue, the Court concluded that allegations of fraud on the FDA or violations of FDA disclosure requirements "conflict with, and are therefore impliedly preempted by, federal law." *Id.* at 348. In the Court's judgment, such claims can interfere with the Agency's determinations regarding the disclosures it wants, when it wants them, and which inducements and sanctions to apply to that end. Illustrating the scope and complexity of those determinations, the Court set forth the FDA's complex disclosure requirements applicable to medical devices, including the submission of prospective labeling and

advertisements, explanations and data regarding the similarities between a proposed device and existing devices, and any additional information the FDA seeks. *Id.* at 348-49. The requirements applicable in this case to prescription drugs are just as rigorous, if not more so. Before prescription drugs can be marketed, the sponsor must submit an extensive New Drug Application, including "full reports of investigations" into the safety and efficacy of the drug. 21 U.S.C. § 355(b)(1)(A) (2000). In addition, extensive and intricate regulations govern the reporting of adverse drug events that occur once the drug is on the market. *See* 21 C.F.R. § 314.80 (2002).

To enforce these disclosure requirements, as the Court noted in *Buckman*, the FDA has at its disposal provisions "aimed at detecting, deterring, and punishing false statements. . . ." 531 U.S. at 349. The FDA has the authority to investigate suspected fraud, 21 U.S.C. § 372 (2000), while citizens may report wrongdoing and petition the Agency to act, 21 C.F.R. § 10.30 (2002). The remedies available to the FDA include injunctive relief against fraud, 21 U.S.C. § 332 (2000), or seizure of the product, *id.* § 334. In addition, the Food, Drug, and Cosmetic Act ("FDCA") mandates that "failure to establish or maintain any record, or make any report, required" by these regulations is subject to criminal prosecution, *id.* §§ 331(e), 333(a), as are false statements to the Agency, 18 U.S.C. § 1001 (2000). In sum, the Court found, the "federal statutory scheme amply empowers the FDA to punish and deter fraud," and the FDA uses "this authority . . . to achieve a somewhat delicate balance of statutory objectives. The balance sought by the [Agency] can be skewed by allowing fraud-on-the-FDA claims under state tort law." 531 U.S. at 348.

In explaining how state litigation regarding fraud on the FDA could overrun the careful lines the FDA has drawn, the Court worried that "complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants – burdens not contemplated by Congress in enacting the FDCA or the MDA [, the Medical Device Amendments]." *Id.* at 350. Companies, the Court predicted, will fear that "their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id.* at 351. That fear will fuel an "incentive to submit a deluge of information that the Administration neither wants nor needs."[2] *Id.*

B. The Court of Appeals Over-Emphasized the Procedural Format of Fraud on the FDA Claims

In reading *Buckman*, the Second Circuit appeared to fixate on this Court's observation that the plaintiffs there, in this Court's words, were not "relying on traditional state tort law which had predated the federal enactments in question," and that to the contrary, "the existence of these federal enactments [was] a critical element in their case." *Buckman*,

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2. For example, in 1997, the FDA stated that it did not wish to receive adverse event reports unless there was an identifiable patient and reporter, a suspect drug and an adverse event, "because reports without such information make interpretation of their significance difficult, at best, and impossible, in most instances." ADVERSE DRUG REACTION REPORTING REGULATIONS WORKING GROUP, GUIDANCE FOR INDUSTRY, POST-MARKETING ADVERSE EXPERIENCE REPORTING FOR HUMAN DRUG AND LICENSED BIOLOGICAL PRODUCTS: CLARIFICATION OF WHAT TO REPORT 3 (1997), http://www.fda.gov/cber/gdlns/advexp.pdf (last visited July 17, 2007). And the FDA has discouraged reporting of adverse events derived from "planned contacts and active solicitation" unless they are "serious" or "unexpected." *Id.* at 3-4.

531 U.S. at 353. The Court of Appeals thus distinguished *Buckman* on the ground that it involved a cause of action specifically for fraud on the FDA, while in this case the Michigan statute incorporates the fraud charge as a prerequisite to traditional tort liability. *See Desiano*, 467 F.3d at 94 ("M.C.L. § 2946(5) did not invent new causes of action premised on fraud against the FDA."). Elaborating on this distinction, the Court of Appeals found that the cause of action here "cannot reasonably be characterized as a state's *attempt* to police fraud against the FDA." *Id.* (emphasis added). Rather, the court held that the "*object* of the legislative scheme was ... to regulate and restrict when victims could continue to recover under preexisting state products liability law," *id.*, and that "the *goal* of preventing or punishing fraud against the FDA in [no] way *motivated* Michigan legislators," *id.* at 94 n.5 (emphasis added). The Court of Appeals therefore concluded that *Buckman* was inapplicable and the presumption against preemption, controlling. *Id.* at 98.

The Court of Appeals' distinction misgauges the focus of *Buckman*. To begin with, there is no hint in *Buckman*, nor in the long line of precedent on conflict preemption, that the presumption against preemption turns on a state's intent to regulate. Nor is there any suggestion that the question whether state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941), depends on whether the state intended it to do so. As in prior preemption cases, the Court in *Buckman* was concerned about the effects of state law, not the intent behind it. To hold otherwise would mean that states could undermine federal regulation so long as they were merely negligent in doing so.

As to the traditional reach of tort claims, an embedded prerequisite of fraud on the FDA in a familiar cause of action, as in this case, is no more rooted in common law doctrine than the stand-alone claim in *Buckman*. The point of the discussion in *Buckman*, which the Court of Appeals missed, was that liability there did not hinge, as is normally the case, on the defendant's communications with the plaintiffs, their doctors or the public, but rather on the defendant's communications with the FDA. And whatever authority the state may have to regulate the relationship between pharmaceutical companies *and the public*, it cannot regulate the relationship between pharmaceutical companies *and the FDA*. The same principle applies here. Under the Michigan statute, liability hinges on Warner-Lambert's communications and relationship with the FDA, which the state may not regulate.

Furthermore, in shifting the focus from the impact of state law to the motivation behind it, from practical consequences to procedural formality, the Court of Appeals shortchanged this Court's concern that the burden of satisfying discordant common law duties and FDA requirements would lead applicants to inundate the Agency with unwanted and unhelpful information. *Buckman*, 531 U.S. at 351. To be sure, the Court of Appeals did touch on this concern. *Desiano*, 467 F.3d at 96-97. The court's logic in dismissing it, however, was both circular and empirically unfounded. The court inferred that pharmaceutical companies would continue to have incentives to flood the FDA with unwelcome disclosures so long as fact-finders in tort cases are allowed to consider evidence of fraud against the Agency and to react to that evidence in assessing liability and punitive damages. *Id.* at 97. Therefore, permitting plaintiffs to prove fraud on the FDA when rebutting a statutory defense to

liability would not, in the court's uncorroborated judgment, amplify those incentives. *Id.* Rather, the court inferred, only stand-alone claims of fraud against the FDA would markedly increase the incentives. *Id.* In other words, because "anything goes" short of a cause of action for fraud on the FDA, only the incremental impact of such a cause of action for fraud could have constitutional significance. But aside from the absence of any basis for confidence in the court's predictions, this argument simply assumes the answer to the question before the court—whether, in fact, "anything goes" short of a cause of action for fraud on the FDA.

Moreover, the Second Circuit's cramped focus on pleading invested the procedural context of *Buckman* with far more significance than this Court intended. *Buckman* addressed a cause of action for fraud on the FDA because that was the claim against the petitioner—who was a consultant, not a manufacturer.[3] Nevertheless, in discussing the potential impact of claims of fraud on the FDA, this Court explicitly addressed "applicants," that is manufacturers. *See Buckman*, 531 U.S. at 350. They—unlike consulting companies—get sued not only for fraud on the FDA, but routinely face claims of negligence, strict liability, fraud, and breach of warranty. Thus, under the reasoning of the court

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3. That *Buckman* involved a consultant, rather than a manufacturer, was happenstance. The trial court held that fraud on the FDA claims against medical device manufacturers were also preempted. *In re: Orthopedic Bone Screw Prods. Liab. Litig.*, No. MDL 1014, 1997 WL 305257, at *3 (E.D. Pa. March 28, 1997), *rev'd*, 159 F.3d 817 (3d Cir. 1998), *rev'd sub nom. Buckman Co. v. Plaintiffs' Legal Comm'n*, 531 U.S. 341 (2001). Because plaintiffs asserted no other cause of action against the consultant, they obtained an order under Fed. R. Civ. P. 54(b) permitting an interlocutory appeal only of the decision regarding the consultant.

below, in a multi-count complaint against a manufacturer, if a plaintiff alleges fraud on the FDA in a separate count, the claim would pose the threat that concerned this Court, skewing the "delicate balance of [the FDA's] statutory objectives," *id.* at 348, and thus would be preempted. But if the plaintiff inserted precisely the same allegations in the other counts for negligence or strict liability, they would not have the same effect and hence would not be preempted. Form is thus more important than substance. As this Court said many years ago in dismissing a comparably flawed argument, "To state the proposition is to refute it." *Howard* v. *Ill. Cent. R.R. Co.*, 207 U.S. 463, 502 (1908).

In short, the Sixth Circuit was correct in *Garcia* when it recognized that tort liability predicated on "*state court* findings of fraud on the FDA," will "raise the same inter-branch-meddling concerns that animated *Buckman.*" 385 F.3d at 966. Those concerns arise regardless of the procedural vehicle for those findings.

II. The Disposition of This Petition Could Affect Tens of Thousands of Cases

As the petition for certiorari demonstrates, cases interpreting *Buckman* have divided along the fault line reflected in *Desiano* and *Garcia.* Like the Second Circuit, a number of district courts and a state court have limited *Buckman* to stand-alone claims of fraud against the FDA. And like the Sixth Circuit, other federal district courts and state courts have assessed whether claims incorporating fraud on the FDA, whatever the procedural format, interfere with the Agency's mission and therefore are preempted. The petition for certiorari discusses these cases in detail.

Cataloging the cases on each side of the divide, however, only begins to convey the pervasiveness of this issue in product liability litigation involving drugs and medical devices, or the sheer number of cases affected. For instance, in the few weeks since the petition was filed, the New Jersey Superior Court handling the Vioxx litigation in that state ruled that federal law does not preempt the New Jersey statute allowing punitive damages only upon proof of fraud on the FDA. The court reasoned that *Buckman* did not apply because "the extensive regulations for medical devices *coupled with* the preemption provision of the MDA indicated sufficient intent of Congress to preempt fraud on the FDA claims." *Cona v. Merck & Co.*, No. ATL-L-3553-05 (N.J. Super. Ct. Law Div. June 8, 2007) (mem.). The absence of such an express preemption provision for prescription drugs, the court concluded, shows that Congress did not intend to permit implied preemption. *Id.* In fact, *Buckman* found implied preemption *despite* the presence of an express preemption provision in the MDA, not because of it. This Court stated that "neither an express pre-emption provision nor a saving clause 'bar[s] the ordinary working of conflict pre-emption principles.'" 531 U.S. at 352 (quoting *Geier v. Am. Honda Motor Co*, 529 U.S. 861, 869 (2000)). The New Jersey court's inverted reading of *Buckman* may affect the more than 15,000 cases pending before that court. *See Vioxx Case List*, http://www.judiciary.state.nj.us/mass-tort/vioxx/vioxxlist_022807.pdf.[4]

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4. Taking a different route toward the same destination, the MDL judge in *In re Vioxx Products Liability Litigation*, 401 F.Supp.2d 565, 593 (E.D. La. 2005), allowed plaintiffs to present "expert" testimony that Merck "was not forthcoming with the FDA with respect to the risks of *Vioxx*," in violation of FDA requirements. In the court's view, *Buckman* was inapplicable because plaintiffs did

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By contrast, in the more than 1000 Vioxx cases consolidated in Texas state court, the trial judge reached the opposite conclusion regarding the Texas statute that makes fraud on the FDA a precondition to liability. *Ledbetter v. Merck & Co., Inc.*, Nos. 2005-59499, 2005-58543, 2007 WL 1181991 (Dist. Ct. Tex., 157th Jud. Dist. Apr. 19, 2007) (Trial Order); Heather Won Tesoriero, *Merck's Vioxx Troubles May Ebb with Ruling Poised to Aid Defense: Expected Case Dismissal Could Weaken Legal Basis for All 1,000 Texas Suits*, WALL ST. J., Apr. 13, 2007, at A3, *available at* http://online.wsj.com/article/SB117641547470168234.html. Thus, the vitality of many thousands of claims involving Vioxx depends in large measure on geography.

Likewise, geography appears determinative in litigation involving diet drugs. In *Bouchard v. American Home Products Corp.*, 213 F.Supp.2d 802, 812 (N.D. Ohio 2002), the court excluded evidence offered to show that the FDA was misled. *See also Flynn v. Am. Home Prods. Corp.*, 627 N.W.2d 342, 349 (Minn. Ct. App. 2001). But in the MDL proceeding, *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001), the court held that an expert witness who was a former FDA employee could testify (a) "about the standard of care in the pharmaceutical industry regarding the manner in which certain information should

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not present causes of action for fraud on the FDA. *Id.* at 587, 595. The holding not only foretells the resolution of preemption motions regarding fraud on the FDA, but virtually guarantees that plaintiffs in the 8,800 cases before that court will invite juries to rely on this evidence. *See* Judicial Panel on Multidistrict Litigation, *Distribution of Pending MDL Dockets* (as of May 14, 2007), http://www.jpml.uscourts.gov/Pending_MDLs/PendingMDL-May-07.pdf [hereinafter "JPML Pending MDLs"] at 4.

be communicated to the FDA; and (b) what FDA officials would have done with certain additional information such as particular adverse event reports." *Id.* at *24. The ruling, if followed by remand courts after *Buckman*, would encourage juries in the 2533 diet drug cases pending in federal court to base liability on their assessment of the proper relationship between Wyeth and the FDA. *See* JPML Pending MDLs at 9.

The pressing need for this Court's guidance stems not only from the cases where courts have already addressed the scope of *Buckman*, but also from thousands of other cases where the issue is pending or necessarily will arise. These cases assert claims under the laws of virtually every state, not just Michigan. For instance, the master complaint in the multidistrict litigation involving the drug Propulsid alleges that, "Defendants failed to warn the FDA of material facts regarding the safety and efficacy of Propulsid, such that this drug would likely never have been approved, and no physician would have been able to prescribe this drug, for use in the United States." Master Class Action Complaint, *In re Propulsid Prods. Liab. Litig.*, MDL No. 1355, 2001 WL 34562410 (E.D. La. Oct. 5, 2001). Consequently, resolution of the question whether plaintiffs can recover damages based in whole or part on fraud against the FDA may affect the outcome in the 362 cases before that MDL Court.[5] *See* JPML Pending MDLs at 4.

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5. Similarly, the Master Complaint in the MDL proceeding involving defibrillators manufactured by Guidant, Inc. alleges that "[w]hile Guidant had provided some information to the FDA, that information was incomplete and misleading and did not adequately disclose the Device defects. Guidant's flawed disclosures did not comply with FDA regulations and violated the conditions of approval

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More deftly, in the multidistrict litigation involving the anti-psychotic drug Zyprexa, many complaints seek to exploit the formalistic line that the Second Circuit and other courts have drawn. These complaints, while alleging that the defendant Eli Lilly "withheld from and/or misrepresented to the [FDA] required information that was material and relevant to the performance of the product," profess that the plaintiffs do not "make a claim *as such* for 'fraud on the FDA,' but Plaintiffs do allege that these misrepresentations and/or concealment and/or omissions are a contributing, producing and/or proximate cause of Plaintiffs' injuries." *See, e.g.*, Plaintiffs' Original Complaint for Personal Injuries and Demand for Jury Trial ¶ 86, *Hanson v. Eli Lilly & Co.*, No. 1:06CV05275, 2007 WL 1143404 (E.D.N.Y. Mar. 22, 2007) (emphasis added). In other words, the plaintiffs do not assert a cause of action for fraud on the FDA but seek to recover damages for it anyway. There are 1786 cases pending in the Zyprexa multi-district proceeding. *See* JPML Pending MDLs at 7.

Despite their massive scale, these matters still represent only a small slice of the litigation affected by the issue before this Court. Of direct concern to this Court is *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006), *cert. granted*, (U.S. Jun. 25, 2007) (No. 06-179). This Court recently

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(Cont'd)

for the Devices." Plaintiffs' Master Complaint for Personal Injury, Economic Loss, Third Party Payor and Medicare Secondary Payor Act Claims, Including Class Actions Jury Demand ¶ 82, *In re: Guidant Defibrillators Prods. Liab. Litig.*, No. 05-md-1708, 2006 WL 3327027 (D. Minn. Apr. 24, 2006). Thus again, the question of whether plaintiffs can offer evidence that the FDA was defrauded may influence the resolution of the 1361 cases pending before that court. *See* JPML Pending MDLs at 5.

granted review to decide whether tort claims involving medical devices subject to premarket approval ("PMA") are expressly preempted if they seek to impose requirements different from or in addition to those dictated by the FDA. *Id.* But failure to resolve the issue in this petition could render whatever decision this Court might reach in *Riegel* virtually inoperative. The ruling in *In re Medtronic, Inc. Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886 (D. Minn. 2006), highlights the problem. The MDL court there, addressing the same issue presented in *Riegel*, rejected express preemption based largely on the plaintiffs' allegations that Medtronic had not been forthcoming when obtaining the FDA's approval of the PMA. *Id.* at 895. Aside from the effect on the 1042 cases pending in that proceeding, *see* JPML Pending MDLs at 5, the court's reasoning would make fraud on the FDA a reliable end run around the MDA's express preemption provision. Plaintiffs will simply claim—on information and belief, no less—that in securing approval of the PMA, the manufacturer concealed the truth from the FDA, and that would be enough to allow a case to go forward.

Blazing such a facile path around the express preemption provision, moreover, would effectively nullify *Buckman* itself. Despite this Court's unanimous ruling, a claim of fraud on the FDA would become an essential element of plaintiffs' proof of liability in virtually every product liability case involving a PMA-approved device. Such a result would engender a far greater level of interference with the Agency than the intrusiveness the Court found so problematic in *Buckman*. In addition, if this approach infects pharmaceutical litigation, plaintiffs could potentially circumvent preemption even where the FDA ordered a manufacturer to do or say exactly what plaintiffs challenge. That question is at issue in more than 20 MDL proceedings, as well as many other state

and federal litigations, involving claims of injury from FDA-approved drugs. *See* Judicial Panel on Multidistrict Litigation, *Products Liability Litigations*, http://www.jpml.uscourts.gov/Pending_MDLs/Products_Liability/products_liability.html.

The FDA sought to block this end run when it promulgated its regulations on prescription drug labeling in 2006. In the preamble to the regulations, the Agency reaffirmed that "under existing preemption principles, FDA approval of labeling ... preempts conflicting or contrary State law." Requirements on Content and Format of Labeling for Human Prescription Drugs and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). In providing examples of such conflicts, the FDA recognized that a company should not be able to procure an FDA decision by fraud and then assert that decision as a bar to state law claims. *Id.* at 3936. But consistent with *Buckman*, the FDA concluded that such considerations should limit preemption of conflicting state requirements *only* where the "*FDA has made a finding* that the sponsor withheld material information relating to the statement" at issue. *Id.* (emphasis added). To forsake that limitation would compound one type of intrusion—conflicts with FDA requirements—with another—disruption of the FDA's enforcement regime.

The point here is not that *Buckman* precludes any claim, argument or evidence regarding the basis for FDA decisions. Rather, it is that the Second Circuit's ruling *allows* virtually any collateral attack under state law on FDA determinations, provided the attack is encapsulated in a cause of action labeled as something other than a stand-alone fraud on the FDA claim. The ruling here is so expansive that it would leave *Buckman* inoperative in the many thousands of cases

where fraud on the FDA is at issue. It would potentially open a gaping loophole to the express preemption provision of the MDA—at issue in thousands more cases. And it would resurrect form pleading, where using (or avoiding) the right "magic words" potentially would moot the question whether states can impose liability on companies for obeying FDA instructions—implicated in thousands more litigations. Thus, failure to delineate the scope of *Buckman* now may result in untold numbers of cases being wrongly decided. When this Court ultimately does resolve the issue, the dislocation could be overwhelming, potentially necessitating reversals, retrials, and delays. In the meantime, as this Court predicted in *Buckman*, the multitude of assorted fraud on the FDA claims will disrupt the Agency's "measured approach" to enforcement and precipitate a flood of unsolicited information to the FDA, thereby interfering with the Agency's congressionally mandated responsibilities. This is exactly the result *Buckman* sought to avoid.

CONCLUSION

The Court of Appeals misread *Buckman*. That error, and the split in authority it reflects, is important to the courts, to industry, to federal regulators, and to litigants. This Court should resolve the issue now.

PLAC urges the Court to grant the petition for certiorari.

Respectfully submitted,

HUGH F. YOUNG, JR.
PRODUCT LIABILITY ADVISORY COUNCIL, INC.
1850 Centennial Park Dr.
Suite 510
Reston, VA 20191
(703) 264-5300

ROBERT N. WEINER
Counsel of Record
ELIZABETH J. BETTA
ARNOLD & PORTER LLP
555 12th Street, N.W.
Washington, DC 20004
(202) 942-5000

Attorneys for Amicus Curiae

APPENDIX

APPENDIX

Corporate Members of the Product Liability Advisory Council

as of 6/29/2007

3M
A.O. Smith Corporation
Altec Industries
Altria Corporate Services, Inc.
American Suzuki Motor Corporation
Andersen Corporation
Anheuser-Busch Companies
Appleton Papers, Inc.
Arai Helmet, Ltd.
Astec Industries
BASF Corporation
Bayer Corporation
Bell Sports
Beretta U.S.A Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
Black & Decker (U.S.) Inc.
BMW of North America, LLC
Boeing Company
Bombardier Recreational Products
BP America Inc.
Bridgestone Americas Holding, Inc.
Briggs & Stratton Corporation
Brown-Forman Corporation
CARQUEST Corporation
Caterpillar Inc.
Chevron Corporation

Appendix

Continental Tire North America, Inc.
Cooper Tire and Rubber Company
Coors Brewing Company
Crown Equipment Corporation
DaimlerChrysler Corporation
The Dow Chemical Company
E & J Gallo Winery
E.I. DuPont De Nemours and Company
Eaton Corporation
Eli Lilly and Company
Emerson Electric Co.
Engineered Controls International, Inc.
Estee Lauder Companies
Exxon Mobil Corporation
Ford Motor Company
Freightliner LLC
Genentech, Inc.
General Electric Company
General Motors Corporation
GlaxoSmithKline
The Goodyear Tire & Rubber Company
Great Dane Limited Partnership
Harley-Davidson Motor Company
The Heil Company
Honda North America, Inc.
Hyundai Motor America
Illinois Tool Works, Inc.
International Truck and Engine Corporation
Isuzu Motors America, Inc.
Jarden Corporation
Johnson & Johnson
Johnson Controls, Inc.

Appendix

Joy Global Inc.,
Joy Mining Machinery Kawasaki Motors Corp., U.S.A.
Kia Motors America, Inc.
Koch Industries
Kolcraft Enterprises, Inc.
Komatsu America Corp.
Kraft Foods North America, Inc.
Lincoln Electric Company
Magna International Inc.
Mazda (North America), Inc.
Medtronic, Inc.
Merck & Co., Inc.
Michelin North America, Inc.
Microsoft Corporation
Mine Safety Appliances Company
Mitsubishi Motors North America, Inc.
Nintendo of America, Inc.
Niro Inc.
Nissan North America, Inc.
Nokia Inc.
Novartis Consumer Health, Inc.
Novartis Pharmaceuticals Corporation
Occidental Petroleum Corporation
PACCAR Inc.
Panasonic
Pfizer Inc.
Porsche Cars North America, Inc.
PPG Industries, Inc.
Purdue Pharma L.P.
Putsch GmbH & Co. KG
The Raymond Corporation
Raytheon Aircraft Company

Appendix

Remington Arms Company, Inc.
Rheem Manufacturing
RJ Reynolds Tobacco Company
Sanofi-Aventis
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.
St. Jude Medical, Inc.
Sturm, Ruger & Company, Inc.
Subaru of America, Inc.
Synthes (U.S.A.)
Terex Corporation
Textron, Inc.
TK Holdings Inc.
The Toro Company
Toshiba America Incorporated
Toyota Motor Sales, USA, Inc.
TRW Automotive
UST (U.S. Tobacco)
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.
Whirlpool Corporation
Wyeth
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.